K122757

510(k) SUMMARY

OCT 5 2012

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237
Date Summary Prepared:	September 6, 2012
Device:	Trade Name: ACE Cholesterol Reagent Classification: Class 1, meets limitations of exemption per 21 CFR § 862.9(c)(4) and (c)(9) Common/Classification Name: Enzymatic Esterase-Oxidase, Cholesterol (21 CFR § 862.1175) Product Code CHH Trade Name: ACE HDL-C Reagent Classification: Class 1, meets limitations of exemption per 21 CFR § 862.9(c)(4) and (c)(9) Common/Classification Name: LDL & VLDL Precipitation, Cholesterol Via Esterase-Oxidase, HDL (21 CFR § 862.1475) Product Code LBS Trade Name: ACE LDL-C Reagent Classification: Class 1, meets limitations of exemption per 21 CFR § 862.9(c)(4) and (c)(9) Common/Classification Name: System, Test, Low Density, Lipoprotein (21 CFR § 862.1475) Product Code MRR Trade Name: ACE Triglycerides Reagent Classification: Class 1, meets limitations of exemption per 21 CFR § 862.9(c)(4) and (c)(9) Common/Classification Name: Lipase Hydrolysis/Glycerol Kinase Enzyme, Triglycerides (21 CFR § 862.1705) Product Code CDT
Predicate Devices:	Predicates:

ACE Cholesterol Reagent (k113262)
ACE HDL-C Reagent (k113262)
ACE LDL-C Reagent (k113262)
ACE Triglycerides Reagent (k113262)

Similarities	**Candidate Device**	**Predicate Device**
510(k) #	k122757	K113262
Company	Alfa Wassermann Diagnostic Technologies, LLC	Alfa Wassermann Diagnostic Technologies, LLC
Name	ACE Axcel Clinical Chemistry System, ACE Cholesterol Reagent	ACE Axcel Clinical Chemistry System, ACE Cholesterol Reagent
Intended Use/ Indications for Use	Same	The ACE Cholesterol Reagent is intended for the quantitative determination of cholesterol concentration using the ACE Axcel Clinical Chemistry System. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.
Instrument Platform	Same	ACE Axcel Clinical Chemistry System
Basic Principle	Same	Enzymatic method for cholesterol
Reagent Composition Reactive Ingredients	Same	4-Aminoantipyrene p-Hydroxybenzoic acid Cholesterol oxidase (Nocardia) Cholesterol esterase (porcine pancreas and Pseudomonas) Peroxidase (Horseradish)
Differences		
Sample Type	Serum and lithium heparin plasma	Serum

Similarities	Candidate Device	Predicate Device
510(k) #	k122757	K113262
Company	Alfa Wassermann Diagnostic Technologies, LLC	Alfa Wassermann DiagnosticTechnologies, LLC
Name	ACE Axcel Clinical Chemistry System, ACE HDL-C Reagent	ACE Axcel Clinical Chemistry System, ACE HDL-C Reagent
Intended Use/ Indications for Use	Same	The ACE HDL-C Reagent is intended for the quantitative determination of high density lipoprotein cholesterol (HDL-C) concentration using the ACE Axcel Clinical Chemistry System. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.
Instrument Platform	Same	ACE Axcel Clinical Chemistry System
Basic Principle	Same	Detergent solubilization of HDL to selectively measure HDL cholesterol using an enzymatic method.
Reagent Composition Reactive Ingredients	Same	Cholesterol oxidase (E. coli) Peroxidase (Horseradish) N, N-bis(4-sulphobutyl)-m-toluidine-disodium salt Accelerator Ascorbic oxidase (Curcurbita sp.) 4-Aminoantipyrene Cholesterol esterase (Pseudomonas)
Differences		
Sample Type	Serum and lithium heparin plasma	Serum

Similarities	Candidate Device	Predicate Device
510(k) #	k122757	K113262
Company	Alfa Wassermann Diagnostic Technologies, LLC	Alfa Wassermann Diagnostic Technologies, LLC
Name	ACE Axcel Clinical Chemistry System, ACE LDL-C Reagent	ACE Axcel Clinical Chemistry System, ACE LDL-C Reagent
Intended Use/ Indications for Use	Same	The ACE LDL-C Reagent is intended for the quantitative determination of low density lipoprotein cholesterol (LDL-C) concentration using the ACE Axcel Clinical Chemistry System. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.
Instrument Platform	Same	ACE Axcel Clinical Chemistry System
Basic Principle	Same	Detergent solubilization of LDL to selectively measure LDL cholesterol using an enzymatic method
Reagent Composition Reactive Ingredients	Same	Cholesterol esterase Cholesterol oxidase Peroxidase 4-Aminoantipyrine Ascorbic acid oxidase Buffer N,N-bis (4-sulfobutyl)-m-toluidine, disodium salt
Differences		
Sample Type	Serum and lithium heparin plasma	Serum

	Similarities	Candidate Device	Predicate Device
	510(k) #	k122757	K113262
	Company	Alfa Wassermann Diagnostic Technologies, LLC	Alfa Wassermann Diagnostic Technologies, LLC
	Name	ACE Axcel Clinical Chemistry System, ACE Triglycerides Reagent	ACE Axcel Clinical Chemistry System, ACE Triglycerides Reagent
	Intended Use/ Indications for Use	Same	The ACE Triglycerides Reagent is intended for the quantitative determination of triglyceride concentration using the ACE Axcel Clinical Chemistry System. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.
	Instrument Platform	Same	ACE Axcel Clinical Chemistry System
	Basic Principle	Same	Coupled enzymatic reaction
	Reagent Composition Reactive Ingredients	Same	4-Aminoantipyrine adenosine 5'-triphosphate p-Chlorophenol Glycerol phosphate oxidase (Microorganism) Lipase (Pseudomonas) Peroxidase (Horseradish) Glycerol kinase (Cellulomonas)
	Differences		
	Sample Type	Serum and lithium heparin plasma	Serum
Device Descriptions:	In the ACE Cholesterol Reagent assay, cholesterol esters in serum are completely hydrolyzed by cholesterol esterase to free cholesterol and free fatty acids. The cholesterol liberated by the esterase, plus any endogenous free cholesterol, are both oxidized by cholesterol oxidase to yield hydrogen peroxide. The hydrogen peroxide then acts to oxidatively couple p-hydroxybenzoic acid and 4-amin-oantipyrine in a reaction catalyzed by peroxidase, producing a red colored		

	quinoneimine complex which absorbs strongly at 505 nm. The amount of chromogen formed, determined by measuring the increase in absorbance, bichromatically at 505 nm/647 nm, is directly proportional to the cholesterol concentration in the sample. The HDL-C Reagent assay utilizes two reagent bottles, the second containing a unique detergent. This detergent solubilizes only the HDL lipoprotein particles, thus releasing HDL cholesterol to react with the cholesterol esterase and cholesterol oxidase, in the presence of a chromogen to produce color. The detergent also inhibits the reaction of the cholesterol enzymes with LDL, VLDL and chylomicron lipoproteins by adsorbing to their surfaces. The amount of chromogen formed, determined by measuring the increase in absorbance bichromatically at 592/692 nm, is directly proportional to the HDL cholesterol concentration in the sample. In the ACE LDL-C Reagent assay, detergent 1 solubilizes non-LDL lipoprotein particles (HDL, VLDL and chylomicrons) and releases cholesterol. The cholesterol is consumed by cholesterol esterase and cholesterol oxidase in a non-color forming reaction. In a second reaction, detergent 2 solublizes the remaining LDL particles and forms peroxide, via the enzymes cholesterol esterase and cholesterol oxidase. The peroxide, in the presence of peroxidase and two peroxidase substrates, 4-aminoantipyrine and DSBmT, results in a purple-red color. The amount of color formed, determined by measuring the increase in absorbance bichromatically at 544/692 nm, is directly proportional to the LDL cholesterol concentration in the sample. In the ACE Triglycerides Reagent assay, triglycerides in serum are hydrolyzed by lipase to form glycerol and free fatty acids. In the presence of adenosine triphosphate (ATP) and glycerol kinase, the glycerol is converted to glycerol-1-phosphate and the ATP to adenosine diphosphate. Glycerol-1-phosphate is oxidized by glycerol phosphate oxidase to yield hydrogen peroxide. The hydrogen peroxide then acts to oxidatively couple p-chlorophenol and 4-aminoantipyrine in a reaction catalyzed by peroxidase, producing a red colored quinoneimine complex which absorbs strongly at 505 nm. The amount of chromogen formed, determined by measuring the increase in absorbance bichromatically at 505 nm/692 nm, is directly proportional to the triglycerides concentration in the sample.
Intended Use:	Indications for Use: The ACE Cholesterol Reagent is intended for the quantitative determination of cholesterol concentration in serum and lithium heparin plasma using the ACE Axcel Clinical Chemistry System. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

	The ACE HDL-C Reagent is intended for the quantitative determination of high density lipoprotein cholesterol (HDL-C) concentration in serum and lithium heparin plasma using the ACE Axcel Clinical Chemistry System. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE LDL-C Reagent is intended for the quantitative determination of low density lipoprotein cholesterol (LDL-C) concentration in serum and lithium heparin plasma using the ACE Axcel Clinical Chemistry System. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE Triglycerides Reagent is intended for the quantitative determination of triglyceride concentration in serum and lithium heparin plasma using the ACE Axcel Clinical Chemistry System. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.
Technological Characteristics:	The ACE Cholesterol Reagent is composed of a single reagent bottle. The reagent contains 4-aminoantipyrine, p-hydroxybenzoic acid, cholesterol oxidase, cholesterol esterase and peroxidase. The ACE HDL-C Reagent is composed of two reagent bottles (Buffer and Color Reagent). The reagents contain Good's buffer, cholesterol oxidase, peroxidase, N,N-bis(4-sulphobutyl)-m-toluidine-disodium salt, ascorbic oxidase, cholesterol esterase 4-aminoantipyrine and a detergent. The ACE LDL-C Reagent is composed of two reagent bottles (Buffer and Color Reagent). The reagents contain MES Buffer (pH 6.3), detergent 1, cholesterol esterase, cholesterol oxidase, peroxidase, 4-aminoantipyrine, ascorbic acid oxidase, detergent 2 and N,N-bis(4-sulphobutyl)-m-toluidine-disodium salt. The ACE Triglycerides Reagent is composed of a single reagent bottle. The reagent contains aminoantipyrine, adenosine 5'-triphosphate, p-chlorophenol, glycerol phosphate oxidase, lipase, peroxidase and glycerol kinase.
Performance Data:	Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Axcel Clinical Chemistry System included matrix comparison data and precision/reproducibility data. *Precision/Reproducibility:*

Precision was evaluated following the guideline EP10-A3. Two replicates each of 3 levels of samples at clinically relevant decision levels were tested twice a day on 5 separate days, yielding 20 replicates total. The results are presented in the tables below:

Analyte Cholesterol mg/dL	Precision (SD, %CV)				
	Mean	Within-Run	Between Run	Between Day	Total
Serum Low	150.9	2.3, 1.5%	0.0, 0.0%	0.8, 0.6%	2.4, 1.6%
Serum Mid	252.5	2.5, 1.0%	2.5, 1.0%	0.0, 0.0%	3.6, 1.4%
Serum High	522.4	5.8, 1.1%	3.5, 0.7%	0.0, 0.0%	6.8, 1.3%
Plasma Low	130.2	2.4, 1.8%	0.5, 0.4%	1.1, 0.8%	2.7, 2.1%
Plasma Mid	338.0	4.1, 1.2%	0.0, 0.0%	0.0, 0.0%	4.1, 1.2%
Plasma High	550.8	6.6, 1.2%	0.0, 0.0%	4.4, 0.8%	7.9, 1.4%

Analyte HDL-C mg/dL	Precision (SD, %CV)				
	Mean	Within-Run	Between Run	Between Day	Total
Serum Low	47.6	1.8, 3.8%	0.9, 1.9%	0.3, 0.7%	2.0, 4.3%
Serum Mid	76.4	1.9, 2.5%	0.0, 0.0%	0.5, 0.7%	2.0, 2.6%
Serum High	105.7	1.8, 1.7%	0.0, 0.0%	1.5, 1.4%	2.4, 2.2%
Plasma Low	41.3	1.1, 2.6%	0.0, 0.0%	0.7, 1.6%	1.3, 3.1%
Plasma Mid	71.2	0.7, 1.0%	0.3, 0.4%	1.0, 1.3%	1.2, 1.7%
Plasma High	102.9	2.2, 2.1%	1.5, 1.5%	0.0, 0.0%	2.7, 2.6%

Analyte LDL-C mg/dL	Precision (SD, %CV)				
	Mean	Within-Run	Between Run	Between Day	Total
Serum Low	92.4	2.1, 2.3%	0.7, 0.8%	1.0, 1.1%	2.4, 2.6%
Serum Mid	159.5	3.0, 1.9%	2.0, 1.2%	0.7, 0.4%	3.7, 2.3%
Serum High	345.6	5.9, 1.7%	3.9, 1.1%	0.0, 0.0%	7.1, 2.1%
Plasma Low	78.7	1.2, 1.6%	0.6, 0.8%	1.1, 1.4%	1.8, 2.3%
Plasma Mid	214.8	5.5, 2.6%	0.7, 0.3%	0.3, 0.2%	5.6, 2.6%
Plasma High	364.8	5.9, 1.6%	2.5, 0.7%	7.2, 2.0%	9.6, 2.6%

Analyte Triglycerides mg/dL	Precision (SD, %CV)				
	Mean	Within-Run	Between Run	Between Day	Total
Serum Low	67.5	0.9, 1.4%	0.5, 0.7%	0.9, 1.4%	1.4, 2.1%
Serum Mid	330.2	2.5, 0.8%	1.6, 0.5%	1.6, 0.5%	3.4, 1.0%
Serum High	596.6	3.6, 0.6%	0.0, 0.0%	2.3, 0.4%	4.3, 0.7%
Plasma Low	69.5	0.8, 1.2%	1.1, 1.5%	1.8, 2.5%	2.2, 3.2%
Plasma Mid	341.5	2.5, 0.7%	2.4, 0.7%	0.0, 0.0%	3.5, 1.0%
Plasma High	601.0	6.0, 1.0%	7.3, 1.2%	9.6, 1.6%	13.5, 2.3%

	Linearity/assay reportable range: Refer to previously cleared submission k113262 *Traceability, Stability, Expected values (controls, calibrators, or methods):* Refer to previously cleared submission k113262 Expected values/Reference range: Refer to previously cleared submission k113262 *Detection Limit:* Refer to previously cleared submission k113262 *Analytical specificity:* Refer to previously cleared submission k113262 *Method Comparison/Bias Determination:* Refer to previously cleared submission k113262 *Matrix Comparison:* Matrix comparison studies were carried out following guideline EP9-A2-IR. The studies consisted of running a series of paired serum (x) and lithium heparin plasma (y) specimens in singlicate with varying levels of analyte that cover the assay's dynamic range on the ACE Axcel Clinical Chemistry System. Results were analyzed using Deming regression.

		Reagent	**Range**	**Results ACE Axcel Serum vs. Plasma**
		Cholesterol 54 pairs	24-574 mg/dL	Slope: 0.987 Intercept: -1.9 Correlation: 0.9987 Std. Error Est: 4.7 Confidence Interval Slope: 0.974 to 1.001 Confidence Interval Intercept: -4.6 to 0.8
		HDL 53 pairs	6-112 mg/dL	Slope: 1.011 Intercept: -1.1 Correlation: 0.9981 Std. Error Est: 1.5 Confidence Interval Slope: 0.993 to 1.028 Confidence Interval Intercept: -2.0 to -0.2
		LDL 54 pairs	10-428 mg/dL	Slope: 1.006 Intercept: -1.6 Correlation: 0.9981 Std. Error Est: 4.7 Confidence Interval Slope: 0.989 to 1.023 Confidence Interval Intercept: -3.7 to 0.5
		Triglycerides 55 pairs	34-994 mg/dL	Slope: 0.992 Intercept: -3.6 Correlation: 0.9993 Std. Error Est: 7.2 Confidence Interval Slope: 0.981 to 1.002 Confidence Interval Intercept: -6.2 to -0.9
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 5 2012

Alfa Wassermann Diagnostic Technologies, LLC
c/o Hyman Katz, Ph. D.
Vice President, Quality and Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

Re: k122757
Trade/Device Name: ACE Cholesterol Reagent, ACE HDL-C Reagent, ACE LDL-C Reagent, ACE Triglycerides Reagent
Regulation Number: 21 CFR§ 862.1175
Regulation Name: Cholesterol (Total) Test System
Regulatory Class: Class I, meets limitations per 21 CFR§ 862.9(c)(4) (9)
Product Code: CHH, LBS, MRR, CDT
Dated: September 6, 2012
Received: September 7, 2012

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Devices and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH'S Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-576-. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800 638-2041 or (301) 796-5680 or at its Internet address http://www.fda/gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __k122757_____

Device Name: ACE Cholesterol Reagent

Indications for Use: The ACE Cholesterol Reagent is intended for the quantitative determination of cholesterol concentration using the ACE Axcel Clinical Chemistry System. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Device Name: ACE HDL-C Reagent

Indications for Use: The ACE HDL-C Reagent is intended for the quantitative determination of high density lipoprotein cholesterol (HDL-C) concentration using the ACE Axcel Clinical Chemistry System. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D)	AND/OR	Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use

510(k) Number (if known): __k122757_____

Device Name: ACE LDL-C Reagent

Indications for Use: The ACE LDL-C Reagent is intended for the quantitative determination of low density lipoprotein cholesterol (LDL-C) concentration using the ACE Axcel Clinical Chemistry System. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Device Name: ACE Triglycerides Reagent

Indications for Use: The ACE Triglycerides Reagent is intended for the quantitative determination of triglyceride concentration using the ACE Axcel Clinical Chemistry System. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D)	AND/OR	Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
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